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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,884	10/15/2003	Jennifer L. Harris	18062G-003211US	7551
20350	7590	11/30/2006		EXAMINER
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			SRIVASTAVA, KAILASH C	
			ART UNIT	PAPER NUMBER
			1657	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/686,884	HARRIS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Dr. Kailash C. Srivastava	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 21 August 2006.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 84-114 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 84-114 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____.                                     |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____.                         |

## **DETAILED ACTION**

1. Request for continued examination (i.e., RCE) under 37 CFR §1.114, including the fee set forth in 37 CFR §1.17(e), was filed in this application on 21 August 2006 after a Notice of Appeal filed 17 January 2006 and a Final action mailed 15 July 2005. Since this application is eligible for continued examination under 37 CFR §1.114, and the fee set forth in 37 CFR §1.17(e) has been timely paid, the finality of the previous Office action mailed 15 July 2005 has been withdrawn pursuant to 37 CFR §1.114. Applicants' submission filed 21 August 2006 has been entered. Accordingly an RCE has been established and the action on RCE follows.
2. Applicants' Terminal Disclosure over U.S. Patent 6, 680,178 filed 21 August 2006 pursuant to 37 C.F.R. §1.321 (c) is acknowledged and entered.
3. The Art Unit Location to which your application has been assigned at the United States Patent and Trademark Office (i.e., (USPTO) is changed to Art Unit 1657.
4. The assigned Examiner to your application at the USPTO is Dr. Kailash C. Srivastava. To aid in correlating any papers for this application, all further correspondence regarding this application (i.e.. U.S. Non-Provisional Application Number 10/686,884) should be directed to Examiner Kailash C. Srivastava in Art Unit 1657.

### **Claims Status**

5. Claim 1-83 are cancelled.
6. Claims 84-114 have been added.
7. Claims 84-114 are pending.

### ***Election/Restriction***

8. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - Group I – Claims 84-90 drawn to a material linked to a solid support, wherein said material has a particular structure as claimed and having a fluorogenic moiety, classified under Class 530, Subclass 337, for example.

- Group II – Claims 91-95 and 99-103 drawn to a library of fluorogenic peptides with or without a solid support, classified under Class 530, Subclass 300, for example.
- Group III – Claims 96-98 drawn to a method to determine a peptide sequence specificity profile of an enzymatically active protease, classified under Class 435, Subclass 7.95, for example.
- Group IV – Claims 104-106 drawn to a method to determine a peptide sequence specificity profile of an enzymatically active protease comprising contacting said protease with a library of fluorogenic peptides, classified under Class 435, Subclass 23, for example.
- Group V – Claims 107-111 drawn to a library of fluorogenic amino acid amides with or without a solid support, classified under Class 530, Subclass 326, for example.
- Group VI – Claims 112-114 drawn to a method to determine an amino acid specific sequence specificity profile of an enzymatically active protease comprising contacting said protease with a library of fluorogenic amino acid amides, classified under Class 435, Subclass 4, for example.

#### **Inventions are Independent and Distinct**

9. Inventions in Groups II and V are related to each other as sub-combinations disclosed as not usable together in a single combination. The products of each of groups II and V are distinct, each from the other. The product of Group II is a peptide, whereas the product of Group V invention is an amide. Further, the product of Group II requires that the sub-libraries be comprised of tetra- or hexa-peptides, which limitation is not a requirement for the composition in groups I or in Group V.

Inventions in Group I is related to inventions in each of Groups II and V as combination/sub-combination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the sub-combination as claimed for patentability, and (2) that the sub-combination has utility by itself or in other combinations

[MPEP § 806.05(c)]. In the instant case, the sub-combination (i.e., the products in any one of Groups II or V) does not require the particulars of the combination (i.e., Group I product) as claimed for patentability because the combination, by itself would be patentable even if the sub-combination was known and non-obvious, assuming that the prior art does not teach or suggest the presence of the additional ingredients recited in the combination claims. The sub-combination (i.e., the products in any one of Groups II or V) has utility of its own because it will be applicable for a number of applications, e.g., purification of a protein, or in drug discovery.

Inventions in Groups I-II and V are related to inventions in Groups III-IV and VI as products and use thereof. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product [MPEP § 806.05(h)]. The method of invention encompassed in Group VI invention for example can be accomplished with a number of commercial peptide or amide libraries of a variety of sequences. Similarly, product of invention in Group I for e.g., would be applicable to determine the activity or specificity of any enzyme not only a protein or of any proteinase/protease enzyme.

Inventions in Groups III-IV and V are unrelated to each other because each one of them is directed to different inventions that are not connected in design, components, operation and/or effect. These inventions are independent since they are not disclosed as capable of use together. They have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone (MPEP § 806.04, MPEP § 808.01). In the instant case, for example invention recited in claims encompassed in Group III is a method to determine the peptide sequence specificity of a protease, whereas invention encompassed in Group VI is directed to a method to determine the amino acid specificity of a protease, wherein the fluorogenic amino acid amide sequence library may or may not be immobilized to a solid support. Furthermore, the steps in said method are distinctly different and the end product is also different. Thus, inventions in Groups III and VI or IV have different steps and different effect and therefore, those inventions cannot be practiced together.

The inventions discussed above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. Moreover, the search for each one of the above inventions is not coextensive particularly with regard to the literature search. For example the search strategy for the inventive Group I would require the incorporation of structure indicated in Claim 84, whereas inventive Group II search strategy will require a search for the structure in Claim 91 or 94. Similarly, different strategies will have to be developed for each of the inventive Groups III-VI with either a different structure or different key words for a text search. Furthermore, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification (Classification is a combination of Class and subclass), and their recognized diverse subject matter, restriction for examination purposes as indicated is proper.

### **Species Election**

10. This application contains claims directed to different compositions/methods comprised of a variety of ingredients. Therefore, if the applicants elect anyone of Groups I-VI above, the applicants must also make election of species by electing a single species from each of the following categories for each of the Groups as indicated:
  - i. For inventive Group I, only one among an amine protecting group, amino acid residue or a peptide sequence among those in Claims 85-88;
  - ii. For Groups II and IV, Only one among tetra- or hexapeptide listed in Claims 94 or 99; and

iii. For Groups III-IV and VI, Only one protease, among: aspartic, cysteine, metallo- and serine proteases listed in Claims 98, 106 and 114.

11. Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR §1.143).

12. In accordance with 37 CFR §1.499, applicant is required that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR §1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species [MPEP § 809.02(a)].

13. Applicants are reminded that upon the cancellation of claims to a non-elected invention and species, the inventorship must be amended in compliance with 37 CFR §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR §1.48(b) and by the fee required under 37 CFR §1.17(I).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

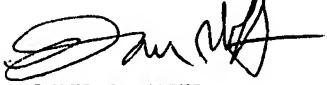
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status

information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Kailash C. Srivastava, Ph.D.  
Patent Examiner  
Art Unit 1657  
(571) 272-0923

November 22, 2006

  
DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 1287657